IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

THE STATE OF ILLINOIS, EX REL., KWAME RAOUL, ATTORNEY GENERAL, Plaintiff, v. ELI LILLY AND COMPANY; NOVO NORDISK INC.; SANOFI-AVENTIS U.S. LLC; EVERNORTH HEALTH, INC. (FORMERLY EXPRESS SCRIPTS HOLDING COMPANY); EXPRESS SCRIPTS, INC., EXPRESS SCRIPTS ADMINISTRATORS, LLC; ESI MAIL PHARMACY, INC.; EXPRESS SCRIPTS PHARMACY, INC.; MEDCO HEALTH SOLUTIONS, INC.; CVS HEALTH CORPORATION; CVS PHARMACY, INC; CAREMARK RX, L.L.C.; CAREMARKPCS HEALTH, L.L.C.; CAREMARK, L.L.C.; UNITEDHEALTH GROUP, INC.; OPTUMRX INC.; AND OPTUMINSIGHT, INC., Defendants.	Case No. 1:23-CV-00170

MEMORANDUM OF LAW IN SUPPORT OF MANUFACTURERS' MOTION TO DISMISS PLAINTIFF'S COMPLAINT UNDER FED. R. CIV. P. 12(B)(6)

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Illinois's lawsuit challenges conduct that is both permitted and required by law and which has been public knowledge for over a decade. Drug manufacturers Eli Lilly and Company, Novo Nordisk Inc., and Sanofi-Aventis U.S. LLC ("Manufacturers") have long and openly paid rebates to middlemen known as Pharmacy Benefit Managers (the "PBMs"). As everyone acknowledges, Manufacturers must pay those rebates to ensure their diabetes medications are on the formularies that the PBMs maintain for insurers, which determine whether millions of patients have access to those medications. These rebates are a standard practice in the pharmaceutical industry, are not unique to insulin, and are contemplated by state and federal statutes.

Nevertheless, the State of Illinois, through its Attorney General, argues that the Manufacturers' undisputed *compliance* with these statutes is somehow unlawful. Although federal and state law expressly authorize rebates and Manufacturers' price reporting practices, the State's principal claim is that Manufacturers violated the Consumer Fraud Act, 815 Ill. Comp. Stat. 505/1 *et seq.*, because the list prices Manufacturers reported to third-party compendiums did not subtract rebates they paid to PBMs, and because the price of Manufacturers' diabetes medications is "egregious." Illinois also tacks on a claim for unjust enrichment based on the same theory. But these allegations cannot state a claim for several independent reasons.

First, the Consumer Fraud Act claim fails under the law's express safe-harbor provision, which forbids claims that would "impose higher disclosure requirements" than those "sufficient to satisfy federal regulations." *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 941 (7th Cir. 2001). Federal law instructs manufacturers to report list prices *without* accounting for "discounts, rebates or reductions in price." 42 U.S.C. §§ 1396r-8(a)(1), 1395w-3a(c)(6)(B). And the Illinois Legislature has considered the policy concerns the Attorney General raises here and declined to control Manufacturers' list prices, as the Attorney General argues courts should. The Consumer

Fraud Act's safe harbor prohibits the State from asking the Court to enforce a new, contradictory way of setting and reporting the price of Manufacturers' medicines that circumvents Congress and the Legislature's policy judgments.

Second, this theory would still fail without the safe harbor because the Complaint does not allege Manufacturers' practices were deceptive or unfair. Illinois's theory is that Manufacturers' reported list prices were "deceptive" because they were unrelated to the "net prices" Manufacturers realized after accounting for rebates. But Illinois does not allege Manufacturers ever suggested that there was a relationship between list and net prices. Rather, Manufacturers represented that their list prices did not include rebates, just as federal law requires.

The State fares no better with its claim that Manufacturers' insulin prices constitute an "unfair practice" because they are supposedly "egregious." Under binding precedent, an "unconscionably high price generally is insufficient to establish a claim for unfairness" under the Consumer Fraud Act. *Siegel v. Shell Oil Co.*, 612 F.3d 932, 935 (7th Cir. 2010). The Consumer Fraud Act thus requires Illinois to *further* allege that Manufacturers violated a standard of conduct established by law or rule, which Illinois cannot do. Illinois also ignores its obligation to allege that the challenged conduct (payment of rebates) has no "countervailing benefits" because it cannot do so. As Illinois repeatedly acknowledges, Manufacturers must pay rebates to ensure that patients can access affordable medication through their commercial insurance.

Third, Illinois's unjust enrichment claim fails for all the same reasons as the Consumer Fraud Act claim, because it is based on the same conduct. This claim also fails on its own terms: the State admits that contracts cover the alleged misconduct, and the existence of these contracts bars an unjust enrichment theory. In addition to that dispositive defect, Illinois also does not allege—as it must—that Manufacturers retain a benefit conferred by the State or consumers. That

omission is unsurprising given that Illinois admits that Manufacturers sell their medications solely to wholesalers and that net prices have remained constant.

Fourth, the five-year statute of limitations bars this suit. Not only does the Complaint recycle the factual allegations from another complaint filed six years ago against the same Manufacturers alleging the same so-called scheme, but Manufacturers have been disclosing their prices and rebating practices for over a decade. Nothing here is new and it is all time-barred.

The Court should dismiss Illinois's claims against Manufacturers with prejudice.

BACKGROUND

I. The Distribution of Branded Prescription Drugs.

Manufacturers are pharmaceutical companies that research, develop, manufacture, and sell prescription drugs, including insulin and other diabetes medications. Compl. ¶¶ 5, 38–75, 253. Manufacturers do not sell insulin directly to patients, insurers, or health plans. Instead, Manufacturers sell their medicines to wholesalers, which then sell the medicines downstream to pharmacies. *Id.* ¶ 280 & Fig. 12. Illinois alleges that some manufacturers also sell medicines to mail-order pharmacies that dispense medicines to patients. *Id.*

The only price Manufacturers set is the "list price" for sales to wholesalers. *Id.* ¶¶ 280, 282. The "list price" is aptly named the Wholesale Acquisition Cost, or "WAC," because it is the cost at which wholesalers acquire Manufacturers' medicines. *Id.* Although Manufacturers set the WAC—and only the WAC—for their diabetes medications, the prices charged by other downstream actors "differ[]." *Id.* ¶¶ 281–83, 298 & Fig. 12. After wholesalers purchase medications at the WAC, they resell them to pharmacies at a separately negotiated price. *Id.* Pharmacies then sell medications to patients at still different prices. *Id.* The price a patient pays to a pharmacy for medication may be reimbursed in full or in part by the patient's health plan, depending on each plan's benefit design. *Id.* It may also be reduced by patient assistance programs

offered by Manufacturers. *Id.*; *see also id.* ¶ 474.

PBMs work directly with health plans and insurers to manage and administer prescription drug coverage for insured patients. *Id.* ¶¶ 110, 164, 453. To that end, PBMs "establish standard formulary offerings (*i.e.*, approved drug lists)" that determine whether a drug is "covered by health insurance." *Id.* ¶ 7. PBMs' control over their formularies gives the PBMs "prodigious bargaining power" over Manufacturers. *Id.* ¶¶ 9, 351. As the State explains, "unless [PBMs] include a drug on one of their standard formularies, it is not available to 80% of Illinois's citizens." *Id.* ¶

This feature of the healthcare industry requires Manufacturers to compete fiercely for formulary access to ensure that patients have affordable access to their diabetes medications. Placement on a formulary means that insurance will cover a particular medication, making it more affordable and accessible to consumers. *Id.* ¶¶ 7–11, 337 & Fig. 12. By contrast, a drug's exclusion from a formulary, or its placement on unfavorable terms, can restrict patients' access to that drug, thwarting a Manufacturer's ability to get affordable drugs to those patients. *Id.* As the Complaint acknowledges, Manufacturers "must obtain preferrable formulary position" if they "want their drugs to be prescribed and paid for." *Id.* ¶¶ 10, 358–60.

PBMs use this leverage to negotiate the manufacturer rebates that are at the heart of the Complaint. Rebates are generally discounts, measured as a percentage of WAC, that a drug manufacturer pays to a PBM each time a covered patient buys any branded prescription drug—not just diabetes medications. *Id.* ¶¶ 20, 340, 377; Sood, Neeraj, *et al.*, *The Association Between Drug Rebates and List Prices*, Leonard D. Schaeffer Center for Health Policy & Economics (Feb. 2020), *cited at* Compl. ¶ 365. Historically, PBMs have also required other types of payments from manufacturers, including other fees and discounts, which the Complaint groups with rebates and calls "Manufacturer Payments." Compl. ¶ 20 n.2. Manufacturers do not have visibility into how

the PBMs use rebates, although a portion is often passed along to the health plans and insurers that are the PBMs' clients, while the PBMs keep some of the payments for themselves. *Id.* ¶¶ 375, 378. In turn, the insurers can use the portion of rebates they receive from PBMs to offset prescription costs, reduce premiums, or increase their own cash flow. *Id.* ¶ 290 & Fig. 12.

The State has long known that rebates are an embedded—and legally required—feature of the U.S. healthcare system. Since 1991, the Centers for Medicare & Medicaid Services ("CMS") has required manufacturers to enter into "rebate agreement[s]" with federal and state entities. 42 U.S.C. § 1396r-8(a)(1). Generally, "drug manufacturers" *must* "agree to rebate to the states the difference between the manufacturer's normal price and its 'best price' to any customer." *Wal-Mart Stores*, *Inc. v. Kickrehm*, 101 F. Supp. 2d 749, 757–58 & n.5 (E.D. Ark. 2000) (emphasis omitted).[1] Rebates are a familiar feature of private health insurance coverage, too. *See id.* at 760 n.6.

Illinois is also a participant in this system: it operates a health plan, which contracts with PBMs to provide pharmacy services. Compl. ¶¶ 114, 116, 169, 171. Its Complaint explains how payors—like Illinois—contract with PBMs with respect to the payment of rebates. *Id.* ¶¶ 378–80, 386, 398. The Complaint also acknowledges that industry groups, researchers, local governments, and the U.S. Congress have thoroughly and publicly discussed rebates for years. *Id*. ¶¶ 365–66, 369–70, 374, 393–96, 437, 443. So have Manufacturers—including at congressional hearings about the "significant demand for rebates" from PBMs. *Id.* ¶ 358; *see also id.* ¶¶ 357, 359–60. There, Manufacturers explained that higher rebates lead to higher prices because "[s]eventy-five percent of [the reported] price is paid for rebates and discounts to secure [formulary position]."

[1] *See also, e.g.*, *Pharmacy Benefit Management & Rebates*, Medical Services Admin., at 10 (Mar. 21, 2019), https://bit.ly/3Bq4iK2 ("The federal Medicaid Drug Rebate Program … [r]equires a drug manufacturer to enter into, and have in effect, a national rebate agreement in exchange for state Medicaid coverage.").

Id. ¶ 359. They also testified that refusing to provide rebates would have severe consequences because PBMs would stop covering Manufacturers' medications. *Id.* ¶¶ 358–60.

II. Manufacturers Report Their List Prices as Required by Federal Law.

Although Illinois asserts that "[t]here is no transparency in this pricing system," it admits that Manufacturers "self-report WAC" to "publishing compendiums such as First DataBank, Redbook and others who then publish that price." Compl. ¶¶ 282–83. As the charts in its Complaint show, Illinois—and anyone else who wants it—has decades of information on the specific WAC of every insulin medication Manufacturers sell. *See, e.g.*, *id.* Fig. 9 (charting the WAC of Humulin and Novolin from the 1980s to 2021); *see also id.* Figs. 6–8, 10–11.

This reporting system is governed—and authorized—by federal law. Federal law expressly requires that manufacturers do *not* include rebates and other discounts in their reported list prices. Per federal statutes, WAC is "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, *not including* prompt pay or *other discounts, rebates, or reductions in price*." 42 U.S.C. § 1395w-3a(c)(6)(B) (emphasis added). In other words, federal law instructs Manufacturers to include the list price—and only the list price—in the list prices they report. Reporting the "net price"—*i.e.*, WAC less rebates or other discounts—as the WAC would run afoul of this federal requirement.

While the federal government requires manufacturers to exclude rebates and other discounts from the WAC they report, the federal government knows the amount of rebates PBMs receive. Under another federal law, PBMs are required to report the "aggregate amount, and the type of rebates, discounts, or price concessions … that [they] negotiate[]." 42 U.S.C. § 1320b-23(b). The federal government chose *not* to disclose this information publicly. Illinois similarly has laws governing the disclosure of rebates. Specifically, it requires all PBMs to provide their clients with "an annual right to audit" that requires the "full disclosure of any and all rebate

amounts secured" by the PBM from any manufacturer that paid rebates. 215 Ill. Comp. Stat. 5/513b1(b)(5).

III. This Lawsuit

Despite rebates being well known, and despite its own participation in the rebate system, Illinois alleges that Manufacturers and the PBMs engaged in a purported "Insulin Pricing Scheme" that increased the prices that the State and its citizens paid for diabetes medications. Compl. ¶¶ 27–29, 278, 285–88, 441, 443–44, 462. But despite labeling pharmaceutical rebates a "scheme," all Illinois alleges is that the PBMs have used their "complete[] dominat[ion]" of "the pharmacy benefit services market" to require Manufacturers to offer "larger and larger" rebates for formulary access, and that Manufacturers raised their list prices while "largely maintaining their net prices" as a result. *Id.* ¶¶ 340–42, 452, 490. Illinois contends that the "price" of diabetes medications is higher than it should be, and that the PBMs and Manufacturers in turn make more money. *Id.* ¶¶ 27–29, 278, 285–88, 372–73, 441, 443–44, 462.

Although Illinois says that it can bring Consumer Fraud Act and unjust enrichment claims against both the PBMs and Manufacturers, its allegations against Manufacturers are scant. First, Illinois alleges that Manufacturers engaged in deception because (a) they reported their "list price[s]" or "WAC[s]," which are not "reasonably related to the [drugs'] net prices" after accounting for rebates and discounts, and (b) the reported prices were "untethered from the price Manufacturers were paid for the drugs." *Id.* ¶¶ 488–89. Second, Illinois alleges that Manufacturers' list price increases are "unfair" because they render insulin unaffordable for people with diabetes. *Id.* ¶¶ 490–91. It also adds an unjust enrichment claim as a backstop. *Id.* ¶ 494.

Notably, Illinois is not the first to make such claims. The first suit alleging an insulin pricing "scheme" was filed over six years ago, and Illinois copies extensively from that complaint and others filed in the intervening years. *See* Complaint, *Chaires et al. v. Novo Nordisk Inc. et al.,*

No. 3:17-cv-00699 (D.N.J. Feb. 2, 2017), ECF No. 1.

ARGUMENT

Illinois cannot transform the well-known, common practice of paying rebates into an unlawful scheme. Its lead claim under the Consumer Fraud Act is facially defective. All of the supposedly illegal conduct alleged is specifically addressed by federal and state law, and thus immune under the Consumer Fraud Act's safe-harbor provision. And Illinois cannot state a prima facie claim in any event, because there is nothing deceptive or unfair about Manufacturers accurately reporting list prices and paying rebates that they must offer to ensure that patients can access medications through their insurance plans.[2] The backstop claim for unjust enrichment fails for the same reasons. It independently fails because the alleged conduct is barred by the existence of contracts and because Manufacturers have not retained a benefit from Illinois or consumers. Both claims are also time-barred because Illinois sued after the five-year statute of limitations expired.

I. The Safe Harbor Provision Bars Illinois's Claims Under the Consumer Fraud Act.

The Illinois Consumer Fraud Act contains an express safe harbor for "actions or transactions specifically authorized by laws administered by any regulatory body or officer acting under statutory authority of this State or the United States." 815 Ill. Comp. Stat. 505/10h(1).[3] The authorization "need not be express." *Price v. Philip Morris, Inc.*, 848 N.E.2d 1, 42 (Ill. 2005). Rather, conduct is "specifically authorized" as long as the U.S. or Illinois government

[2] Illinois also alleges that Manufacturers misrepresented the "characteristics and benefits" of insulin in violation of Illinois' Uniform Deceptive Trade Practices Act. Compl. ¶ 489. That claim is premised on the same conduct as its Consumer Fraud Act claim—that Manufacturers' list prices are deceptive because they are not "reasonably related to … net prices"—and fails for the same reasons. *Id.*

[3] Illinois's Uniform Deceptive Trade Practices Act similarly exempts "conduct in compliance with the orders or rules of or a statute administered by a Federal, state or local government agency." 815 Ill. Comp. Stat. 510/4; *see People ex rel. Daley v. Datacom Sys. Corp.*, 531 N.E.2d 839, 847 (Ill. App. Ct. 1988).

"contemplated" or "considered, without disapproving," the underlying conduct. *Johnson v. Marshall Field & Co.*, 312 N.E.2d 271, 276 (Ill. 1974) (affirming dismissal of Deceptive Trade Practices Act claim on these grounds). Illinois's claims fail at the threshold because the conduct it challenges was authorized by Congress and the Illinois Legislature, and the State cannot show Manufacturers violated any state or federal law that otherwise governs their conduct.

A. Manufacturers Accurately Reported Their Prices Under Federal Law.

The Consumer Fraud Act's safe harbor forecloses Illinois's claim that Manufacturers misreported their list prices. Although the Complaint contains several variations of this claim, the essence of Illinois's theory is that the "list prices" Manufacturers reported to "publishing compendia" were "false" because they were not "reasonably related" to Manufacturers' "net prices," which account for rebates and other discounts. Compl. ¶¶ 414–16, 419, 488–89.

This theory is not viable because the way Manufacturers report their list prices is specifically authorized—and expressly prescribed—by federal law. As the State acknowledges, the "list price" Manufacturers "self-report" is the "Wholesale Acquisition Cost" or "WAC." Compl. ¶¶ 282–283. "Wholesale acquisition cost" is a defined term under federal law. It means "the manufacturer's ***list price*** for the drug or biological to wholesalers or direct purchasers in the United States, ***not including*** prompt pay or ***other discounts, rebates or reductions in price***." 42 U.S.C. § 1395w-3a(c)(6)(B) (emphases added). That express direction means that Illinois cannot make allegations concerning noncompliance with federal regulations. *See Bober*, 246 F.3d at 941. Reporting a WAC that *includes* rebates, as the State argues Manufacturers should have done, would not be consistent with federal law. Rather, federal law directs Manufacturers to *exclude* rebates from what they report, as the State acknowledges the Manufacturers must do. *Robinson v. Toyota Motor Credit Corp.*, 775 N.E.2d 951, 962–963 (Ill. 2002) (dismissing consumer fraud claim where the Truth in Lending Act did not require disclosure of charges).

Nor can the State rest its claim on an implicit suggestion that Manufacturers should have done more to explain the relationship between WAC and their net prices. That would impose a "higher disclosure requirement" than "sufficient to satisfy federal regulations." *Bober*, 246 F.3d at 941. To state a claim for violation of the Consumer Fraud Act, Illinois must allege that Manufacturers' conduct was inconsistent with federal law. *Id.*; *see also Mario's Butcher Shop & Food Center, Inc. v. Armour & Co.*, 574 F. Supp. 653, 656 (N.D. Ill. 1983) (dismissing claim for failure to allege specific violations of applicable federal law). Illinois's failure to do so dooms its claims, as Illinois courts have held in similar circumstances. In *Lanier v. Associates Finance, Inc.*, for example, the court rejected the plaintiff's argument that a bank should have disclosed additional information when the bank's interest-rate disclosures were consistent with federal requirements. 499 N.E.2d 440, 441–42 (Ill. 1986). There, as here, "the defendant's compliance with the disclosure requirements of [a federal statute] is a defense to liability under the Consumer Fraud Act." *Id.* at 447; *see also Robinson*, 775 N.E.2d at 962–963; *Price*, 848 N.E.2d at 55 (failure to disclose claim was "barred by this court's long-standing rule against imposing additional disclosure requirements beyond those established by statute or agency regulation"). The Manufacturers cannot have violated the Consumer Fraud Act by *complying* with federal law.

B. Manufacturer Rebates Are "Authorized" by Federal and Illinois Law.

Illinois also argues that Manufacturers' list prices are "egregious" and "unfair" because they are too high, and the "price increases … bear no relation to manufacturing or production cost increases or changes in supply and demand conditions." Compl. ¶¶ 490–91. This claim is also foreclosed by the Consumer Fraud Act's safe harbor because the Illinois Legislature chose an entirely different policy solution to address the State's stated concerns about the affordability of Manufacturers' diabetes medications.

Illinois law requires "insurers"—which typically receive a portion of the rebates paid by

Manufacturers to PBMs—to "limit the total amount that an insured is required to pay for a 30-day supply of covered prescription insulin drugs at an amount not to exceed $100." Compl. Fig. 12; 215 Ill. Comp. Stat. 5/356z.4(c). As the Complaint acknowledges, the Legislature chose this method to address the "burden" of prescription drug pricing. Compl. ¶ 491 n.13. It tellingly did not impose additional burdens on manufacturers, cap the price of insulin, limit rebates, or curtail the supposedly "unfair practices" that the State, through the Attorney General, challenges here.

The Consumer Fraud Act makes clear that the Attorney General—on behalf of the executive branch—cannot now bypass the Legislature by asking this Court to take a different approach to the way Manufacturers set or report the price of their insulin medications. The Legislature plainly "contemplated" the supposedly unfair practice, "considered" how to address policy concerns about it, and never "disapproved" the underlying conduct. *Johnson*, 312 N.E.2d at 276. Those legislative decisions put the challenged conduct beyond the reach of the courts unless the Attorney General plausibly alleges the conduct violates state or federal law, *Mario's*, 574 F. Supp. at 656, which it has not attempted to do.

Nor would shifting the responsibility to the courts be practicable. The Complaint is an invitation to the judiciary to step in and control the price of medicine when prices supposedly become "egregious" and the "wellbeing" of people with diabetes is affected. *Id.* ¶ 490. But courts are "ill suited" to make those kinds of legislative judgments. *Verizon Commc'ns Inc. v. L. Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004) (courts should not "act as central planners, identifying the proper price, quantity, and other terms of dealing"); *Nat'l Collegiate Athletic Ass'n v. Alston*, 141 S. Ct. 2141, 2163–64 (2021) ("[J]udges make for poor 'central planners' and should never aspire to the role."). That is why the Consumer Fraud Act tells courts they must give way to the Legislature when it has already weighed in, as it has plainly done here. *Galvan v. Nw. Mem'l*

Hosp., 888 N.E.2d 529, 539 (Ill. App. Ct. 2008) (claim that "rate [plaintiff] was charged was 'exorbitant' and unrelated to the actual costs of providing the medical services … should be directed to the deliberative process of the legislature").

Any attempt by the States to retreat to its argument that price increases do not bear a rational relationship to "manufacturing or production cost increases or changes in supply and demand conditions" also fails. Compl. ¶ 490–91. Illinois acknowledges list prices have increased to accommodate rebate payments. *Id.* ¶ 26 (rebates "are directly responsible for the skyrocketing price of the at-issue diabetes medications"); *see also id.* ¶¶ 20, 340, 344. And paying rebates is also "specifically authorized" under the Consumer Fraud Act. Congress and CMS have repeatedly addressed rebates. Manufacturers are required by federal law to pay rebates to states under the Medicaid program. *See, e.g.*, 42 U.S.C. § 1396r-8(a)(1); *Wal-Mart Stores*, 101 F. Supp. 2d at 757–58 & n.5 ("Congress amended the Medicaid statute in 1990 to require[] that drug manufacturers … agree to rebate to the states the difference between the manufacturer's normal price and its 'best price' to any customer."). Federal law also recognizes Manufacturers' rebates when it excludes them from the "list price" of a drug. 42 U.S.C. § 1395w-3a(c)(6)(B). And Congress requires PBMs to report the rebates they negotiate with manufacturers. 42 U.S.C. § 1320b-23(b). Illinois has similarly passed on the propriety of rebates. It requires manufacturers to pay rebates under the state Medicaid program.[4] And, like the federal government, the Illinois Legislature imposes reporting requirements on the rebates PBMs receive from manufacturers. 215 Ill. Comp. Stat. 5/513b1(b)(5).

[4] Medicaid, *Medicaid Drug Rebate Program* (Dec. 29, 2022), https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html; Medicaid, *Medicaid Pharmacy Supplemental Rebate Agreements* (June 2022), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxxsupplemental-rebates-chart-current-qtr.pdf.

The state and federal governments have addressed the Attorney General's stated concerns with their own policies, and they chose to authorize the conduct challenged here. That choice requires dismissal of Illinois's Consumer Fraud Act claim as a matter of law.

II. Illinois Has Not Pled a Consumer Fraud Act Claim.

Illinois's Consumer Fraud Act claim also must be dismissed because the Complaint's factual allegations do not plausibly state a claim. To state a claim under the Consumer Fraud Act, Illinois must allege "a deceptive or unfair act or practice by the defendant." *Siegel*, 612 F.3d at 934. Illinois attempts to plead both deception and unfairness, but falls short on both.

A. Illinois Has Not Alleged Manufacturers' List Prices Are Deceptive.

A practice is not "deceptive" under the Consumer Fraud Act unless "it creates a likelihood of deception or has the capacity to deceive." *Bober*, 246 F.3d at 938. Courts assess statements from the vantage point of a "reasonable consumer." *Jackson v. Kraft Heinz Foods Co.,* 2022 WL 4591749, at *2 (N.D. Ill. Aug. 3, 2022). This standard "requires more than a mere possibility" that a statement could be "misunderstood by some few consumers viewing it in an unreasonable manner." *Chiapetta v. Kellogg Sales Co.*, 2022 WL 602505, at *3 (N.D. Ill. March 1, 2022). "Rather, the reasonable consumer standard requires a probability that a significant portion of the general consuming public … acting reasonably in the circumstances, could be misled." *Id*. (quoting *Ebner v. Fresh, Inc.*, 838 F.3d 958, 965 (9th Cir. 2016)).

The only alleged deceit is Manufacturers' list price reporting. As discussed, Illinois asserts that these prices are deceptive because they do not include the rebates Manufacturers pay PBMs, making them "untethered" and not "reasonably related" to Manufacturers' "net prices" after accounting for those rebates. Compl. ¶¶ 488–89. These allegations fail to plausibly allege that Manufacturers committed a deceptive practice under the Consumer Fraud Act for several reasons.

First, Illinois never alleges how a reasonable consumer plausibly could be misled by

Manufacturers' list prices. Tellingly, Illinois does not identify any statement where any Manufacturer even *suggested* that list prices accounted for rebates, approximated net prices, or implied that the list price was anything other than the wholesale acquisition cost of their medicines. Indeed, Illinois expressly admits the "prices" that Manufacturers "report" are the "wholesale acquisition cost[s]" of their drugs, and not the "net price[s]" or any other price. Compl. ¶ 283 ("Drug manufacturers self-report WAC … to publishing compendiums such as First DataBank, Redbook and others who then publish that price."). And, as discussed above, excluding rebates from that reported price is required by federal law.

No consumer could have plausibly been misled by Manufacturers' list prices, which Manufacturers said were the list prices, and that Manufacturers reported in a way that complied with the federal government's definition of list price. The State must allege that Manufacturers suggested the list prices were something other than their actual list prices, but it has not done so. *Ahrendt v. Condocerts.com Inc.*, 2018 WL 2193140, at *3 (N.D. Ill. May 14, 2018) (dismissing Consumer Fraud Act claim where "Defendant said nothing to make [Plaintiff] believe that the fees it charged corresponded to its actual costs for providing documents").

Second, any suggestion that Manufacturers should have said more about the relationship between their list prices and the amount they ultimately realized is contrary to settled Illinois law, which "does not require a company to affirmatively share how [a service or] product will affect its own profits." *Ridings v. Am. Fam. Ins. Co.*, 2021 WL 722856, at *5 (N.D. Ill. Feb. 24, 2021). Nor can Illinois claim that Manufacturers should have said more when reporting their list prices (*i.e.* an omission theory) because "the Act [cannot] be used to transform nondeceptive and nonfraudulent omissions into actionable affirmations." *Spector v. Mondelez Int'l, Inc.*, 178 F. Supp. 3d 657, 672 (N.D. Ill. 2016) (internal quotation omitted). "An omission is actionable only

where it is employed as a device to mislead," meaning the "omission" must create "an affirmatively false impression." *Id*. Here, Manufacturers' reported list prices did not create a "false impression" that the list prices were something other than how federal law has long defined them. Anyone can examine the statute to see that rebates are not included with list prices. It follows that merely not disclosing those rebates cannot be a "device to mislead." Because Illinois has not identified—and cannot identify—any "affirmative misstatement," its Complaint is "insufficient to withstand a … motion to dismiss." *Phillips v. DePaul Univ.*, 19 N.E.3d 1019, 1030 (Ill. App. Ct. 2014).

Third, the Consumer Fraud Act does not require Manufacturers to say more about the relationship between rebates and list price because liability under that Act exists only when a defendant conceals a material fact of which it has "almost exclusive knowledge." *Randels v. Best Real Estate, Inc.*, 612 N.E.2d 984, 988 (Ill. App. Ct. 1993). "[P]ublicly available and accessible" facts do not support a claim. *Ridings*, 2021 WL 722856, at *5. Yet according to the Complaint, the relationship between rebates and the list price was well known to Illinois. Compl. ¶¶ 389, 423, 439, 455. Manufacturers publicly disclose that they pay rebates, which are necessary to secure formulary placement. *Id*. at ¶ 337 ("if we were not included in CVS Caremark's standard formulary we wouldn't have access to those 15 million lives"), *id.* ¶¶ 368-70 (collecting Manufacturer testimony). And, as Illinois concedes, Manufacturers have been candid about the relationship between rebate and price increases, given that Eli Lilly told Congress that "[s]eventy-five percent of our [list] price is paid for rebates." *Id*. ¶ 359; *see also id.* ¶ 358 (quoting Novo Nordisk's President: "We spend almost $18 billion in rebates in 2018"); *id.* ¶ 360 (quoting Sanofi's Executive Vice President for External Affairs: "The rebates are how the system has evolved.").[5]

[5] *See also, e.g.*, Eli Lilly and Company Integrated Summary Report (2017), https://assets.ctfassets.net/srys4ukjcerm/3uCCqJ91DEuxu26iQMpUu0/624bc8859fba59e195243ad1dae4b18a/Lilly_2017_Integrated_Summary_Report.pdf ("[A]verage discounts to U.S. list prices have grown from 30 percent to 51 percent in the past five years."). The Court can consider sources which

Information about the rebate system was readily available from other quarters, too. Congress has legislated on rebates, and industry groups, researchers, and local governments have all thoroughly discussed them. *Id.* ¶ 357, 359–60, 365–66, 369–70, 374, 393–96, 437, 443.[6] So have the federal courts: the Tenth Circuit recently noted that rebates were a "widespread" industry practice. *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, 44 F.4th 959, 989 (10th Cir. 2022); *see also In re Rezulin Products Liab. Litig.*, 390 F.Supp.2d 319, 327 (S.D.N.Y. 2005) ("Medco typically received rebates from manufacturers in exchange for including their products in its formularies."); *Wal-Mart Stores*, 101 F. Supp. 2d at 757–58 & n.5 ("drug manufacturers" must "agree to rebate to the states the difference between the manufacturer's normal price and its 'best price' to any customer").

Illinois cannot claim otherwise. Its own Legislature has addressed the difference between list price and net price by giving health plans "audit rights" to examine the difference between what they pay for the medicines at the pharmacy counter and "any and all rebate amounts secured" by PBMs from manufacturers. 215 Ill. Comp. Stat. 5/513b1(b)(5). And it admits it contracts with PBMs to "control[] pharmaceutical drug[] costs" by "secur[ing] contract provisions guaranteeing [payors] all or some portion of the 'rebates' paid by Manufacturers to the PBMs." Compl. ¶¶ 379,

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indicate what "was in the public realm" at the motion to dismiss stage. *United States ex rel. John v. Hastert*, 82 F. Supp. 3d 750, 764 (N.D. Ill. 2015).

[6] *See also, e.g.*, *Prescription Drug Pricing in the Private Sector* at 18, Congressional Budget Office (Jan. 2007), https:// www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf ("Rebate payments from manufacturers are usually shared between the PBMs and health plans."); CVS Caremark Form 8-K (Mar. 29, 2013) ("[D]uring 2012 Johnson & Johnson paid CVS Caremark certain rebates for prescription drug dispenses made by CVS Caremark. Such rebates are usual and customary in the industry … ."); Eli Lilly and Company Form 10-K (Feb. 19, 2016) ("We [have] enter[ed] into arrangements with [PBMs] providing for discounts or rebates on products."); Denise Roland, *Insulin Prices Soar While Drugmakers' Share Stays Flat*, The Wall Street Journal (Oct. 7, 2016), https://www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat ("PBMs get to keep a portion of the rebates … they negotiate"); *Prescription Drug Pricing: Pharmacy Benefit Managers*, Health Policy Brief Series, HealthAffairs, at 1 (Sept. 2017), https://www.healthaffairs.org/do/10.1377/hpb20171409.000178/collectionitem/healthpolicybrief_178. pdf ("PBMs ... negotiate discounts from manufacturers, generally delivered in the form of rebates.").

389, 423, 439, 455. All these examples show the relationship between list price and net price was "publicly accessible and available" to consumers, and especially to the State.

Fourth, Illinois's deceptive acts claim lacks the heightened specificity required by Rule 9(b). Consumer Fraud Act claims of deception "must be pled with the same particularity and specificity as that required under common law fraud." *Spector*, 178 F. Supp. 3d at 664; *Camasta v. Jos. A. Bank Clothiers, Inc.*, 761 F.3d 732, 736–37 (7th Cir. 2014) (claims under the Consumer Fraud Act are analyzed under Rule 9(b) standard if they sound in fraud). This standard requires Illinois to state "the identity of the person making the misrepresentation," the "time, place, and content of the misrepresentation," and the "method by which the misrepresentation was communicated to the plaintiff." *Camasta*, 761 F.3d at 737; *O'Connor v. Ford Motor Co*., 477 F. Supp. 3d 705, 718 (N.D. Ill. 2020) (requiring the "who, what, when, where, and how" of the fraud).

Illinois has not complied with Rule 9(b)'s strictures. There are three Manufacturers, each of whom have regularly reported list prices for a number of different medications over the fifteen-year period covered by the Complaint. Compl. ¶ 13. List prices change, as do the rebates that affect the "net price" after rebates. Yet, Illinois does not differentiate among Manufacturers, much less "specif[y] in the complaint" the "identity and/or role of the *individual employee* involved in the alleged fraud," as it must. *See United States ex rel. Robinson v. Northrop Corp.,* 149 F.R.D. 142, 145 (N.D. Ill. 1993) (emphasis added); *see also DMC Mach. Am. Corp. v. Heartland Mach. & Eng'g, LLC*, 2019 WL 175272, at *5 (S.D. Ind. Jan. 11, 2019) ("[W]e have previously rejected as 'risible' the suggestion that a plaintiff satisfies Rule 9(b) by alleging it was defrauded by a corporate defendant."). Nor does Illinois attempt to identify *which* prices were "artificial," *when* those prices were "reported," or *how* they were "untethered" from the net price. *Petric v. MCY Music World, Inc.*, 862 N.E.2d 1171, 1181 (Ill. App. Ct. 2007) (affirming dismissal of consumer

fraud claims where plaintiff failed to state "what misrepresentations were made, by whom and to whom, when or how they were made"). These failures are not a mere technicality. Defendants are entitled to know "the circumstances constituting fraud" under Rule 9(b), and Illinois's generalized allegations do not come close to satisfying that standard. Fed. R. Civ. P. 9(b).

B. Illinois Has Failed to Adequately Allege Any Unfair Conduct.

Illinois also attempts to allege an "unfair practice" under the Consumer Fraud Act by claiming Manufacturers "egregiously driv[e] up the price of the at-issue drugs," and the "price increases … bear no relation to manufacturing or production cost increases or changes in supply and demand conditions." Compl. ¶¶ 490–91. "When assessing whether a practice is 'unfair' under" the Consumer Fraud Act, courts consider: "(1) whether the practice offends public policy; (2) whether it is immoral, unethical, oppressive, or unscrupulous; and (3) whether it causes substantial injury to consumers." *Toulon*, 877 F.3d 740 (quoting *Cohen v. Am. Sec. Ins. Co.*, 735 F.3d 601, 609 (7th Cir. 2013)). Illinois's allegations meet none of these criteria.

First, Illinois has failed to allege that Manufacturers violated public policy. "The Consumer Fraud Act is concerned with public policy as established by statutes and the common law," *Batson*, 746 F.3d at 833, not just vague assertions of policy goals. This requires Illinois to point to a specific established statute, administrative rule, or common law doctrine. *Boyd v. U.S. Bank, N.A.*, 787 F. Supp. 2d 747, 752 (N.D. Ill. 2011); *Garrett v. RentGrow Inc.*, 2005 WL 1563162, at *3 (N.D. Ill. July 1, 2005) (finding no violation of public policy where plaintiff failed to point to any established statute or common law doctrine). This requirement is particularly rigorous where a plaintiff's unfairness claim is predicated on supposedly high prices. *See Lane v. Direct Energy Serv., LLC*, 2020 WL 3211435, at *4 (S.D. Ill. June 15, 2020) ("price-gouging" scheme did not offend public policy because there was no allegation it violated "a standard of conduct articulated in an existing statute or common law doctrine"). And the standard for what

constitutes an established statute or administrative rule is high: aspirations, policy preferences, and subregulatory guidance do not suffice. *See Washington v. Hyatt Hotels Corp.*, 2020 WL 3058118, at *6 (N.D. Ill. June 9, 2020) (FTC warning letter did not constitute public policy).

For the most part, Illinois relies on its blanket assertion of a public policy that people "should have access to and not be priced out of the at-issue life-saving medications," and claims high prices make that aspiration more challenging. Compl. ¶ 491. But that allegation is nothing more than a claim that prices are too high in the Attorney General's view, which is not actionable under settled Illinois law. *See Siegel*, 612 F.3d at 935.

The only administrative rule that Illinois cites—Ill. Admin. Code tit. 14 § 470.250—offers no help, and thus confirms the lack of a concrete policy. Section 470.250 merely states that "[i]t is an unfair or deceptive act to claim an actual savings from a 'list price,' 'manufacturer's suggested retail price', or term of similar meaning unless the 'list price' is the price at which the product is offered by a reasonable number of sellers in the seller's trade area (for example: "List Price $99, our price $69, save $30.00)." Ill. Admin. Code tit. 14, § 470.250; *see* Compl. ¶ 491. But Illinois does not allege that Manufacturers claim any fake "savings" from their list prices. Compl. ¶ 491 (referencing only PBM conduct). Nor can Illinois allege that the "list price" is not "the price at which the product is offered by a reasonable number of sellers" because Manufacturers sell all their diabetes medications to wholesalers at the "list price"—*i.e.*, the "Wholesale Acquisition Cost" that Manufacturers report. *Id*. ¶¶ 280, 282. In fact, Illinois law, 215 Ill. Comp. Stat. 5/356z.41, lays bare that Illinois does *not* have a policy against Manufacturers' insulin pricing practices. Compl. ¶ 491 n.13. This law limits insulin out-of-pocket spending—not list prices—at $100 per month, by requiring *insurers* to reimburse patients' costs. *Id*. The Legislature looked at insulin pricing and chose *not* to cap the list price Manufacturers charge

wholesalers.

At best, Illinois identifies a policy goal, rather than a policy embodied in a statute or rule. But that is insufficient. In *Batson*, for example, plaintiffs pointed to both specific antitrust laws and vague policy goals of "musical diversity" and "walking [instead of driving]." 746 F.3d at 833. The Seventh Circuit held that there was no violation of public policy under the Consumer Fraud Act where the relevant antitrust statutes were not violated, and further noted: "While Illinois no doubt supports both musical diversity and walking, the Consumer Fraud Act is concerned with public policy as established by statutes and the common law." *Id*. Illinois, no doubt, supports patients having access to insulin (as do Manufacturers). But that alone does not authorize the Court to supplant the political branches.

Second, Illinois has failed to plead that Manufacturers' prices are "immoral, unethical, oppressive, or unscrupulous." Its main argument is that prices are "excessive" and "not based on" factors like "cost of production or research and development." Compl. ¶¶ 30, 419. But an allegation of an "unconscionably high price generally is insufficient to establish a claim for unfairness." *E.g.*, *Siegel*, 612 F.3d at 935 (affirming dismissal of allegations regarding high gasoline prices) (emphasis added); *see also Toulon v. Cont'l Cas. Co.*, 877 F.3d 725 (7th Cir. 2017) (affirming dismissal where insurance company raised premiums by 76%); *Batson v. Live Nation Ent., Inc.*, 746 F.3d 827, 834 (7th Cir. 2014) (affirming dismissal of allegations of unconscionably high ticket prices); *Flores v. United Airlines*, 426 F. Supp. 3d 520, 531-32 (N.D. Ill. 2019) (dismissing complaint alleging unconscionably high travel insurance fees); *Saunders v. Mich. Ave. Nat. Bank.*, 662 N.E.2d 602, 608 (Ill. App. Ct. 1996) (affirming dismissal of Consumer Fraud Act claim based on unconscionably high overdraft fees). Illinois courts have affirmed plaintiffs cannot premise a claim on high prices even where defendants are hospitals, health insurers, medical

suppliers, and the like. *See EBCF Enters., Inc. v. Erie Ins. Exch.*, 572 F. Supp. 3d 489, 498 (N.D. Ill. 2021) ("Plaintiffs allege that defendant's conduct was immoral, because it took advantage of COVID-19 'for its own financial gain.' That does not suffice. Seeking a profit is not inherently immoral, unethical, unscrupulous or oppressive; it is the essence of our free-market economy." (internal citations omitted)); *Galvan* 888 N.E.2d at 529 (affirming dismissal where plaintiff claimed a hospital charged "over double the net price" for an emergency room stay); *Rockford Mem'l Hosp. v. Havrilesko*, 858 N.E. 2d 56 (Ill. App. Ct. 2006) (affirming dismissal of claim that prices were excessive).

Nor has Illinois pled facts in support of its claim that people with diabetes have no choice about the prices they pay. *See* Compl. ¶ 453; *see Fogt v. 1-800-Pack-Rat, LLC*, 74 N.E.3d 186, 199 (Ill. App. Ct. 2017) ("To be oppressive, the conduct must leave the consumer with little alternative but to submit."). Consumers' out-of-pocket insulin cost depends on whether they are insured, their benefit plan design (*e.g.*, "copayment requirements"), and whether they use Manufacturers' affordability programs. *Id.* ¶¶ 286-87, 474. Illinois's Appellate Court has rejected Consumer Fraud Act unfairness claims based on the assertion that an uninsured plaintiff "had no choice but to accept the medical services provided to him at [ ] inflated rates" relative to the prices insured patients pay. *See Galvan*, 888 N.E.2d at 538–39. The court explained that the plaintiff's "contentions" regarding "exorbitant" prices "should be directed to the deliberative process of the legislature." *Id*. All the more so here when the plaintiff is the State of Illinois.

Finally, Illinois fails to allege a "substantial injury" to consumers. It must show the allegedly "unfair practice" is not "outweighed by any countervailing benefits to consumers or competition that the practice produces." *Siegel*, 612 F.3d at 935. Countervailing benefits include "ke[eping a business] competitive" and maintaining consumer access to products. *Donnellan v.*

Travelers Co., Inc., 2022 WL 170046, at *10 (N.D. Ill. Jan. 18, 2022); *Murphy v. Foster Premier, Inc.*, 2018 WL 3428084, at *4 (N.D. Ill. July 16, 2018) (holding that there were countervailing benefits to paying more for a product when access to that product increased).

Here, Illinois never alleges that its injuries are not outweighed by any "countervailing benefits." In fact, Illinois thoroughly explains that Manufacturers' conduct has a substantial "countervailing benefit": ensuring that Manufacturers' medications are placed on the PBMs' formularies, which in turn ensures that patients have affordable access to those medications. As Illinois explains, unless the PBMs "include a drug on one of their standard formularies," it is "not covered by health insurance" and "it is not available to 80% of Illinois's citizens," meaning failing to pay rebates would have made Manufacturers' diabetes medications *more* expensive for *more* people. Compl. ¶¶ 7, 9. Because Manufacturers' conduct keeps insulin on formularies and affordable for the vast majority of Illinois citizens, the practice has "countervailing benefits" under the Consumer Fraud Act and the State's claim must be dismissed. *Accord Donnellan*, 2022 WL 170046, at *10; *Murphy*, 2018 WL 3428084, at *4 (holding that there were countervailing benefits to paying more for a product when access to that product increased); *Kremers v. Coca-Cola Co.*, 712 F. Supp. 2d 759, 768–69 (S.D. Ill. 2010) (holding that there was a countervailing benefit to trade practices where plaintiff could continue to purchase defendant's product).

III. Illinois's Unjust Enrichment Claim Fails.

The unjust enrichment claim can go no further than the Consumer Fraud Act claim. Illinois's unjust enrichment claim is premised on the exact same conduct as its Consumer Fraud Claim Act. Where, as here, one claim is "derivative" of another, the two claims rise and fall together; if the primary "claim falters so too will" the secondary claim. *McMahon v. Bumble Bee Foods LLC*, 148 F. Supp. 3d 708, 715 (N.D. Ill. 2015). Accordingly, since Illinois lacks a viable Consumer Fraud Act claim, the unjust enrichment claim also fails. *See id.* (dismissing unjust

enrichment claim because plaintiff had no viable Consumer Fraud Act claim); *Ass'n Ben. Servs., Inc. v. Caremark RX, Inc.*, 493 F.3d 841, 855 (7th Cir. 2007) ("[W]here the plaintiff's claim of unjust enrichment is predicated on the same allegations of fraudulent conduct …, resolution of the fraud claim … is dispositive of the unjust enrichment claim as well.").

Illinois's unjust enrichment claim also independently fails on the merits for two reasons.

First, unjust enrichment is an obligation "implied in law" in the absence of an agreement between the parties. *Guinn v. Hoskins Chevrolet*, 836 N.E.2d 681, 704 (Ill. App. Ct. 2005). Therefore, "a plaintiff may not state a claim for unjust enrichment when a contract governs the relationship between the parties." *Blythe Holdings, Inc. v. DeAngelis*, 750 F.3d 653, 658 (7th Cir. 2014). Nor can a plaintiff sue non-parties to the contract who allegedly benefit from the contract's performance. *RBS Citizens, N.A. v. Bentley Motors, Inc.*, 2012 WL 1565457, at *3 (N.D. Ill. May 2, 2012) ("[A] party who performs services under a contract cannot sue third parties for unjust enrichment merely because they benefit from that performance."). Illinois pleads itself out of court on this count because it admits that the State—like other health insurers—contracts with PBMs, and Illinois consumers contract with health insurers and pharmacies. Compl. ¶¶ 114, 169, 171, Fig. 12, 346, 378–80, 425, 454. As the Southern District of Texas recently explained in dismissing similar allegations of an insulin-pricing scheme, Illinois cannot use unjust enrichment to revisit contractual terms and "object[] to [an] artificially inflated price that [it] paid." *Harris County v. Eli Lilly and Company*, 2022 WL 479943, at *14 (S.D. Tex. Feb. 16, 2022) (collecting cases). Because "an express contract exists [that] concerns the same subject matter" as Illinois's unjust enrichment claim, "the doctrine of unjust enrichment has no application here." *First Midwest Bank v. Cobo*, 90 N.E.3d 567, 575 (2017); *see Delisle v. McKendree Univ.*, 2021 WL 4402474, at *3 (S.D. Ill. Sept. 27, 2021) (dismissing complaint where unjust enrichment claim incorporated

plaintiff's "admissions that the parties have a contract"); *Nesby v. Country Mut. Ins. Co*., 346 Ill. App. 3d 564, 567 (2004) (affirming dismissal of complaint where "an automobile insurance policy governed the relationship of the parties").

Second, Illinois must show Manufacturers' "retention of a benefit conferred by [Illinois]." *In re Arthur J. Gallagher Data Breach Litig.*, 2022 WL 4535092, at *10 (N.D. Ill. Sept. 28, 2022). But nothing in the Complaint alleges that any Manufacturer received *any* benefit from Illinois or Illinois consumers, much less unjustly. The Complaint makes clear that Manufacturer' net prices remained the same throughout the alleged "scheme." *See* Compl. ¶ 340. In other words, Manufacturers' alleged conduct yielded no actual marginal profit or "benefit" to them. In addition, the Complaint alleges only that wholesalers and some pharmacies purchase medications from Manufacturers, and Manufacturers do not have any relationship or interaction with Illinois, health plans, or any individual consumers. *See* Compl. ¶¶ 280, 290 & Fig. 12, 294. As a result, neither Illinois nor its citizens ever conferred on Manufacturers the benefit of "amounts paid for diabetes medications" or any other "fees and payments." *Id*. ¶ 494.

Illinois cannot rely on fees or payments made by *other parties* (like drug wholesalers) to Manufacturers. To recover for a benefit transferred via a third party, Illinois must establish one of three "limited circumstances": "(1) the benefit should have been given to the plaintiff, but the third party mistakenly gave it to the defendant instead, (2) the defendant procured the benefit from the third party through some type of wrongful conduct, or (3) the plaintiff for some other reason had a better claim to the benefit than the defendant." *Cement-Lock v. Gas Tech. Inst.*, 618 F. Supp. 2d 856, 886 (N.D. Ill. 2009); *Caremark RX, Inc.*, 493 F.3d at 854.

The only theory Illinois conceivably attempted to plead is a benefit procured "through some type of wrongful conduct." But the Complaint makes no effort to explain how it was wrongful for

Manufacturers to charge wholesalers the wholesale price for diabetes medications, which is the only way Manufacturers receive a benefit. Compl. Fig. 12. And "[w]rongful conduct alone will not support an unjust enrichment claim," in any event. Rather, Illinois must allege that it or its consumers "have some interest in the property that a third party gave to the defendant." *Indep. Tr. Corp. v. Fid. Nat. Title Ins. Co. of N. Y.*, 577 F. Supp. 2d 1023, 1050 (N.D. Ill. 2008). Illinois cannot allege that any payments wholesalers provide Manufacturers "belonged to it [or consumers], in any meaningful sense." *Id.*

For the same reason, Illinois has not alleged it has a "better claim" to the "benefit" wholesalers confer on Manufacturers. Wholesalers pay Manufacturers for medications that Manufacturers produce. Compl. ¶¶ 280, 282, Figure 12. Illinois does not claim that the State or Illinois consumers have any entitlement to be paid by wholesalers, much less that its claims "were superior" to Manufacturers'. *See Interlease Aviation Invs. II v. Vanguard Airlines, Inc.*, 2004 WL 1149397, at *12 (N.D. Ill. May 20, 2004) (plaintiff with a contractual claim to funds "on an equal plane" with defendant's could not prevail on "better claim" unjust enrichment theory); *Bovay v. Sears, Roebuck & Co.*, 2017 WL 660595 at *15 (Ill. App. Ct. Jan. 6, 2017) (where the defendant "has not been enriched by any funds from" the named plaintiffs, the court "fail[ed] to see why they would have a 'better claim to the benefit' than" the defendant).

IV. Illinois's Claims Are Time-Barred.

Even if Illinois's claims were legally viable, they would be time-barred. Both claims rest on the premise that Illinois and its consumers were harmed because Manufacturers' list prices for their diabetes medications did not reflect PBM rebates and were thus supposedly "inflated." But Illinois indisputably knew well before the five-year limitations period that list prices exclude rebates. Nor does any tolling doctrine or immunity apply.

A. Each Claim Accrued More than Five Years Ago.

Both of Illinois's claims accrued well before the relevant limitations periods. Illinois law provides that "actions on unwritten contracts, expressed or implied" and "all civil actions not otherwise provided for, shall be commenced within 5 years next after the cause of action accrued." 735 Ill. Comp. Stat. 5/13-205. That limit covers both claims here. Unjust enrichment is based on an implied contract, and the Consumer Fraud Act does not provide a specific, alternative statute of limitations for actions by the Attorney General. *See CitiMortgage, Inc. v. Parille*, 49 N.E.3d 869, 883 (Ill. App. Ct. 2016) ("The limitations period applicable to unjust enrichment claims is five years[.]"); 815 Ill. Comp. Stat. 505/7.

Illinois "kn[e]w or reasonably should [have] know[n]" of the alleged "scheme" long before December 2017 (*i.e.* five years prior to filing suit). *Super Mix of Wis., Inc. v. Nat. Gas Pipeline Co. of Am., LLC*, 167 N.E.3d 149, 157 (Ill. App. Ct. 2020). The Complaint acknowledges the gravamen of its action stretches back at least "the last fifteen years." Compl. ¶ 254; *see id.* ¶ 271 (challenging prices dating back to 2009). News outlets have been publicly discussing rebates' impact on the prices of insulin and other drugs since at least 2012.[7] And Manufacturers similarly discussed the relationship between rebates and drug price publicly throughout that period. To give just a few examples: In 2014, Sanofi said it "had to increase the level of rebates for Lantus® required to maintain favorable formulary positions." *Sanofi*, 2014 Annual Report (Form 20-F) at 11 (Mar. 10, 2015), *available* at https://tinyurl.com/m4udvmbb.[8] In 2013, Novo Nordisk said it

[7] *See* David Tridgell, *Insulin is too expensive for many of my patients. It doesn't have to be*, CHICAGO TRIBUNE (June 23, 2017) (Ex. A); Katie Thomas, *Drug Prices Keep Rising Despite Intense Criticism*, NEW YORK TIMES (Apr. 26, 2016) (Ex. B); Andrew Pollack, *Health Insurers Pressing Down on Drug Prices*, NEW YORK TIMES (June 20, 2014) (Ex. C); Matthew Herper, *Inside the Secret World of Drug Company Rebates*, FORBES (May 10, 2012) (Ex. D). "[I]t is routine for courts to take judicial notice of … newspaper articles … ." *Schmude v. Sheahan*, 312 F. Supp. 2d 1047, 1064 (N.D. Ill. 2004).

[8] As noted above, the Court can consider sources which indicate what "was in the public realm" at the motion to dismiss stage. *United States ex rel. John v. Hastert*, 82 F. Supp. 3d 750, 764 (N.D. Ill. 2015); *see also In re Midway Games, Inc. Sec. Litig.*, 332 F. Supp. 2d 1152, 1155 n.1 (N.D. Ill. 2004) ("The Court may take judicial notice of SEC filings without converting a motion to dismiss to a motion for summary judgment[.]").

paid $5 billion in rebates and other discounts to obtain "formulary status." Novo Nordisk, 2013 Annual Report (Form 6-K) at 64 (Feb. 5, 2014), *available at* https://tinyurl.com/5256uvw9. And, in 2010, Lilly reported that "[i]n response to competitive pressures, [it] ha[d] entered into arrangements with [purchasers] which provide for discounts or rebates on one or more Lilly products." *See* Eli Lilly and Company, 2009 Annual Report (Form 10-K) at 3, 26 (Feb. 22, 2010), *available* at https://tinyurl.com/5n6v4rke (warning of "pressures for increased pharmaceutical discounts and rebates"). These widely available sources—including statements from Manufacturers themselves—confirm that Illinois could have brought its claims well before December 2017. *See Janousek v. Katten Muchin Rosenman LLP*, 44 N.E.3d 501, 505 (2015) (explaining the "statute of limitations may run despite the lack of actual knowledge" and requires only "reasonable belief that the injury was caused by wrongful conduct").

Not only were the facts underlying the claim widely disseminated, the very theory of liability that Illinois advances was first asserted against these very same Manufacturers—and widely reported too—more than five years before filing. As Illinois does here, a putative class of consumers in *In re Insulin Pricing Litigation* filed a complaint targeting a so-called "scheme" in which the same Manufacturers supposedly "inflated" their medications' wholesale acquisition cost to facilitate payment of rebates "in exchange for formulary status." Complaint, *In re Insulin Pricing Litig.*, No. 17-699 (D.N.J. Feb. 2, 2017), ECF No. 1 ("*Insulin Pricing Compl.*") at ¶¶ 14, 21; *see also id.* ¶¶ 2, 10–12 (alleging that manufacturers conspire with PBMs to inflate the spread between list and net prices as part of a "quid pro quo" for formulary access). Illinois premises this lawsuit on the same theory, and frequently copies language verbatim from the *Insulin Pricing* complaint. *Compare e.g., id.* ¶ 55 ("The prescription drug industry consists of an opaque and complex network of entities engaged in multiple distribution and payment structures.") *with*

Compl. ¶ 279 ("The prescription drug industry consists of a deliberately opaque network of entities engaged in multiple distribution and payment structures."); *Insulin Pricing Compl.* ¶ 146 ("[T]hese measures fail to address the structural issues that have given rise to the price hikes … ."") *with* Compl. ¶ 475 ("These affordability measures fail to address the structural issues that have given rise to the price hikes."). As this language shows, the alleged facts underlying this lawsuit have been known—and used by plaintiffs—since long before Illinois filed suit. Its claims are thus time-barred. *Borto v. First Am. Title Co.*, 2017 WL 1270353, at *4 (Ill. App. Ct. Mar. 31, 2017) ("plaintiff should have known of his injury [based on] the public record").

B. No Statute Of Limitations Exception Applies.

Illinois cannot argue that any exception applies to salvage its untimely claims, because it did not plead any exception to the statute of limitations. *See, e.g.*, *Orlak v. Loyola Univ. Health Sys.*, 885 N.E.2d 999, 1009 (Ill. 2007) ("plaintiff must plead" facts supporting fraudulent concealment); *Cassidy v. Derek Bryant Ins. Brokers, Ltd.*, 613 N.E.2d 1201, 1209 (Ill. Ct. App. 1993) (complaint must include "allegations of late discovery"). Nor could it have.

1. Governmental Immunity Does Not Apply.

In certain circumstances, Illinois government entities are immune from statutes of limitations. *Village of DePue. v. Viacom Int'l, Inc.*, 713 F. Supp. 2d 774, 781 (C.D. Ill. 2010). But this immunity applies only when the law creates an "obligation … for the governmental entity to undertake the action." *Id.* at 783–84 (applying statute of limitations where Village was "not legally obligated to [bring suit] and therefore [was] not asserting a right of the general public"). In other words, if a statute merely "authorizes" the Attorney General "to take certain actions," but does not "mandat[e] it to do so," the statute of limitations still applies against the State. *Stafford v. Bowling*, 407 N.E.2d 771, 774 (Ill. App. Ct. 1980); *see also Champaign Cnty. Forest Pres. Dist. v. King*, 683 N.E.2d 980, 982–84 (Ill. App. Ct. 1997) (holding statute of limitations applied where, among

other things, "no provision of the Act [] require[d]" the forest preserve to act).

Illinois's suit is plainly discretionary. The Consumer Fraud Act provides that the Attorney General "***may*** bring an action in the name of the People of [Illinois]." 815 Ill. Comp. Stat. 505/7(a) (emphasis added). Or the Attorney General "***may***" "issue subpoenas," "conduct hearings," "promulgate rules and regulations," perform investigations, and much more. 815 Ill. Comp. Stat. 505/4, 505/3 (emphasis added). Indeed, the Consumer Fraud Act provides a menu of potential enforcement options, each of which lies within the Attorney General's discretion. *See Stafford*, 407 N.E.2d at 773–74 (finding governmental entity's power discretionary where it had "an arsenal of measures it may take"). Because the Attorney General has "no duty" to sue, his claims are "not immune from the applicable statute of limitations." *See People ex rel. Ill. Dep't of Lab. v. Tri State Tours, Inc.*, 795 N.E.2d 990, 994–95 (Ill. App. Ct. 2003); *People ex rel. Hartigan v. Agri-Chain Prod., Inc.*, 586 N.E.2d 535, 538 (Ill. App. Ct. 1991) (applying statute of limitations where, among other things, there was "no duty on the part of the State or the Department to act").

2. The Continuing Violation Doctrine Does Not Apply.

The continuing violations doctrine similarly fails to salvage the Complaint from being time barred. The doctrine is a "limited exception to the general rule of accrual," which applies only to "a certain sort of injury." *Cothron v. White Castle Sys., Inc.*, 477 F. Supp. 3d 723, 730 (N.D. Ill. 2020). Specifically, it applies to "cumulative" violations, in which no injury exists until a "series of wrongful acts blossoms into" an actionable harm. *Limestone Dev. Corp. v. Village of Lemont.*, 520 F.3d 797, 801 (7th Cir. 2008); *see also Cunningham v. Huffman*, 609 N.E.2d 321, 325 (Ill. 1993) (applying doctrine to medical negligence, because "a single dosage of radiation or medicine might be harmless, whereas treatment over time might be either disabling or even fatal").

Illinois has not alleged a continuing violation. It contends Manufacturers violated the statute each time they "publish[ed] prices for the at-issue drugs" and that Illinois and consumers

are injured when they pay "price[s] … based upon … artificially inflated list prices." Compl. ¶¶ 27, 114, 488–89. This alleged wrongdoing and injury did not "blossom" within the limitations period because "[n]othing about the repeated or ongoing nature of [Manufacturers'] conduct affected the nature or validity of [Plaintiff]'s suit." *Rodrigue v. Olin Emps. Credit Union*, 406 F.3d 434, 443 (7th Cir. 2005). The continuing violation doctrine therefore has no application here.

3. Illinois Does Not Allege Fraudulent Concealment.

Fraudulent concealment fares no better as Illinois does not allege "affirmative acts … designed to prevent the discovery of the action." *Clay v. Kuhl*, 727 N.E.2d 217, 223 (Ill. 2000). Rather, its suit is premised on Manufacturers' *public* representations. *See* Compl. ¶¶ 15–16, 261–77, Figs. 1–11. And Manufacturers publicly disclosed the relevant facts—that they pay rebates to the PBMs to compete for formulary access—well before the limitations period. *See supra*, Part III.A; *Cnty. Bd. of Sch. Trs. of DuPage Cnty. v. Ass'n of Franciscan Fathers*, 364 N.E.2d 691, 699 (Ill. App. Ct. 1977) ("The rule that the statute begins to run only from the discovery of the fraud does not apply when the party affected might with ordinary care have discovered it."). Illinois has long known or "by ordinary care could have discovered" Manufacturers' allegedly "inflated" prices. *Dancor Int'l, Ltd. v. Friedman, Goldberg & Mintz*, 681 N.E.2d 617, 624 (Ill. App. Ct. 1997); Compl. ¶ 488. Fraudulent concealment does not excuse its delay in filing suit.

CONCLUSION

For all of these reasons, Manufacturers respectfully request that the Court dismiss the claims against them in their entirety with prejudice.

Dated: March 6, 2023

Respectfully submitted,

/s/ Ryan J. Moorman

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CERTIFICATE OF SERVICE

I, Ryan J. Moorman, an attorney, certify that on March 6, 2023, a true and accurate copy of the foregoing Memorandum of Law in support of Manufacturers' Motion to Dismiss was served upon counsel of record at the addresses indicated by CM/ECF electronic notification.

/s/ Ryan J. Moorman

Exhibit A

Insulin is too expensive for many of my patients. It doesn't have to be.

By David M. Tridgell
Washington Post • Jun 23, 2017 at 8:35 am

Expand

(Franck Fife / AFP/Getty Images)

At age 15, I developed an unquenchable thirst and frequent urination, and lost 20 pounds. I had developed Type 1 diabetes, an autoimmune disease that destroyed my body's ability to produce insulin. Without insulin, I would have eventually developed a condition called diabetic ketoacidosis, which is lethal without (and even sometimes with) treatment.

Years later, I'm a practicing endocrinologist. I could never have imagined back when I first started taking insulin that one day I would have so many patients who could not afford the medication because of skyrocketing prices. When the drug was discovered in 1921, the original patent was sold to the University of Toronto for $1 so that no one else could patent it and "secure a profitable monopoly."

Numerous improvements later, insulin is produced by a three-company oligopoly. When the first of the newer insulin "analogs," Humalog, hit the market in 1996, it sold for $21 a vial. Today, vials of analog insulins, including Humalog, sell for about $300. Patients with Type 1 diabetes typically require two or three vials of insulin per month, but patients who are more resistant to insulin, such as those with Type 2 diabetes, may require six or more.

A recent paper in the Journal of the American Medical Association found that insulin nearly tripled in cost from 2002 to 2013. A lawsuit filed in January accuses insulin companies of price collusion for allegedly raising prices repeatedly and in lockstep to match their competitors. Prices have gotten so bad that the American Diabetes Association recently launched an online petition at MakeInsulinAffordable.org, which has been signed by more than 248,000 people.

Because insulin is so expensive, some people take less than their prescribed dose, causing higher blood sugars, which may lead to preventable, very expensive complications such as kidney failure, blindness, amputation, heart attacks or even death.

Unfortunately, the American Health Care Act (AHCA) passed by the House last month would let states allow insurance companies to charge people more for preexisting conditions such as diabetes. This may leave more people unable to afford insurance and make it even more difficult for patients with already high premiums and deductibles to afford insulin.

While current law protects patients with preexisting conditions better than the AHCA would, too many people with diabetes are still going without proper medical care. One of my patients, whom I'll call "Joe" to protect his identity, lost his insurance, then developed ketoacidosis because he couldn't afford to pay $600 monthly for two vials of insulin. He didn't die, but he required a costly stay in an intensive-care unit.

Pressure on drugmakers has started to bring small changes. But they're not enough. In response to rising costs, Novo Nordisk will limit future price increases to single-digit hikes per year. Eli Lilly will provide insulin at up to 40 percent off for patients on high-deductible plans. (The downside is that it may not count toward their deductibles.)

Drug companies also offer savings cards that lower patients' co-pays. However, these cards steer patients toward newer, more expensive insulins. And most cards may not help if the insulin the patient takes isn't on their insurance provider's formulary. Plus, such programs may save patients money, but the insurance companies don't save anything, so the costs are likely to be shifted back to patients through higher premiums, deductibles or co-pays.

Endocrinologists like me spend far too much time deciding what patients can afford instead of making sound medical decisions. I deal with these issues nearly every day. Some doctors are uncomfortable discussing costs with patients; many patients are embarrassed to admit they can't afford medication, and some won't acknowledge they aren't taking their full dosages. The physician may then increase the dose, or with Type 2 diabetes may add another drug, when the real issue is that the patient isn't taking the right amount. Since it is so common that patients cannot afford insulin, I've posted the American Diabetes Association petition in each of my practice's exam rooms, and if patients don't bring up cost as an issue, I will frequently point to the petition as an icebreaker. I ask if they have difficulty affording their insulin and medications, and I let them know they aren't alone.

Like some other doctors, I have transitioned many patients with Type 2 diabetes onto older, less costly insulins. I try not to do that for patients with Type 1 diabetes, because these older insulins cause more dangerous low blood sugars. But sometimes I have no choice: It's either cheaper insulin or no insulin.

Our system has additional issues that may heap more straw onto patients' already strained backs - such as insurers' "quantity limits." My patient "Mike" uses 40 units of insulin per day. A box of five insulin pens contains 1,500 units and should last Paul 37 days. Since that is more than a 30-day supply, his insurer charges him a 60-day co-pay. The cutoff depends on the policy: For some, a 31-day supply will trigger a 60-day co-pay. Sometimes this problem manifests itself in reverse: "Mary" needs three vials of insulin to last at least one month. But three vials lasts her 33 days, so when she refills her prescription for a month of insulin, she is dispensed only two vials - a 22-day supply - for which her insurer charges a 30-day co-pay. Sometimes patients are allowed "up to" a 90-day supply, so they are dispensed five vials (which might work out to a 77-day supply) instead of the six vials they were prescribed (a 92-day supply). From the patient's perspective, this "co-pay overcharging" or "under-dispensing" feels like getting one dozen golden eggs for the price of two dozen.

Why do we pay so much more for insulin and other medications in the United States than people do in the rest of the world? Many factors drive prices up. Half a dozen companies may be involved with a drug before it reaches the patient, and each may mark up the cost. Unlike in many countries, there are no government-set limits on what companies can charge. These include manufacturers, wholesalers, pharmacies and pharmacy benefit managers (PBMs), which serve as the middlemen between insurers and drugmakers. PBMs negotiate which drugs are on an insurance company's formulary; they can receive a "rebate" from pharmaceutical companies when drugs make it to formularies. These "rebates" result in inflated list prices that the insurer never pays. (In other countries with nationalized health care, there's no such middleman.) When people pay a co-pay, they don't pay the list price, either. The only people who do are patients who haven't meet their deductible, are in the Medicare "donut hole" or are uninsured - and these people are the hardest hit.

We also live in one of the only two countries in the world (New Zealand is the other) that allow direct-to-consumer advertising for prescription medications. Pharmaceutical companies spend billions on advertising, and those expenses become juicy tax deductions. Finally, while many countries with single-payer systems negotiate drug prices, our Medicare system by law is barred from doing so.

All that complexity - and all the opportunities for profit - leaves patients to be squeezed by the weight of the system when they go to fill their prescriptions.

And it gets even worse. "Tim" ran out of insulin for the first time in his life last year because his insurance provider allowed him to pick up only one vial at a time, and he didn't realize he'd used it up until it was too late. "Brian," a Medicaid patient, requires six vials of insulin per month, three vials each of short-acting and long-acting varieties. Yet he, too, is not allowed to pick up more than one vial of each at a time. Medicaid won't dispense a 90-day supply, because many patients frequently change insurance, and many Medicaid providers don't want to give away a month or two of free insulin. That's understandable - insurers have a bottom line.

But properly managing diabetes requires a lot of work and can be a tremendous burden. These sorts of limitations and frequent pharmacy trips make it that much harder, and they magnify patients' anxiety about running out of insulin and getting seriously ill. Vials can fall and shatter. Insulin exposed to high or low temperatures becomes ineffective. Mail-order shipments may arrive late.

Anyone who's taking insulin should always have at least two vials on hand for emergency backup. Having only one vial is simply not safe - it creates anxiety, and can mean preventable hospital admissions or even death in some cases. It feels like driving on an eighth of a tank of gasoline in the middle of nowhere.

My experience is limited to Minnesota, and I can find no published peer-reviewed data on these practices. Internet forums discuss them often, though, and I have spoken with academic endocrinologists from both coasts who tell me my experience with patients is common in their states as well.

All of these problems could be fixed. We should require pharmacies and insurers to dispense a minimum 30-day supply and make sure patients have a second vial on hand for emergencies. Let's prorate co-pays for patients who are dispensed more than a 30- or 90-day supply, rather than rounding their co-pays up. Insurance companies could decide to do this themselves, but since they're unlikely to do so, it should be legislated at the state or federal level. We should also eliminate co-pay savings cards and require insurers to charge the lowest co-pay for insulin to encourage good blood sugars and reduce hospitalizations.

If Congress were truly serious about addressing access to lifesaving medication, it would overhaul the whole system and eliminate tax write-offs for drug advertising to consumers (or better yet, eliminate this advertising altogether), force more transparency into the pharmaceutical market and PBM rebate system, investigate those rebates and how and why PBMs and manufacturers raise prices, and allow Medicare to negotiate drug prices.

Insulin is a necessity. It's time we return to the spirit of that original $1 patent, put people before profits, and rein in these greedy and unjust cost increases.

Washington Post

David M. Tridgell is a board-certified endocrinologist. He practices outside of Minneapolis.

Exhibit B

The New York Times | https://www.nytimes.com/2016/04/27/business/drug-prices-keep-rising-despite-intense-criticism.html

Drug Prices Keep Rising Despite Intense Criticism

By Katie Thomas

April 26, 2016

4 MIN READ

From the campaign trail to the halls of Congress, drug makers have spent much of the last year enduring withering criticism over the rising cost of drugs.

It doesn't seem to be working.

In April alone, Johnson & Johnson raised its prices on several top-selling products, including the leukemia drug Imbruvica, the diabetes treatment Invokana, and Xarelto, an anti-clotting drug, according to a research note published last week by an analyst for Leerink, an investment bank. Other major companies that have raised prices this year include Amgen, Gilead and Celgene, the analyst reported.

Makers have raised prices on brand-name drugs by double-digit percentages since the start of the year, according to interviews with executives at Express Scripts and CVS Caremark, two major drug-benefit managers. And a report last week by the research firm IMS Health found that in 2015, list prices for drugs increased more than 12 percent, in line with the trend over the five previous years.

"It used to be the drug companies only took one price increase a year," said Dr. Steve Miller, chief medical officer at Express Scripts. "Now what they're doing is taking multiple price increases multiple times a year."

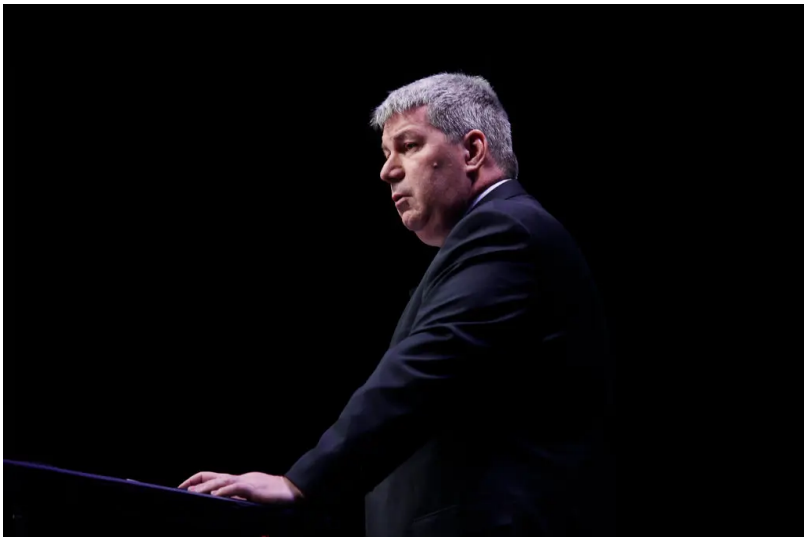
That scrutiny on pricing is likely to continue on Wednesday with the Senate testimony of J. Michael Pearson, the chief of Valeant Pharmaceuticals International, which has come to be viewed as an industry pariah after profiting for years on drastic price increases on old drugs. Mr. Pearson, who is stepping down as chief next month, has been subpoenaed to testify before the Senate Special Committee on Aging, which is investigating the drug-pricing issue.

List prices do not tell the full picture. Much like the inflated room rates posted on the back of a hotel door, drug list prices don't show the rebates and other discounts that insurers and pharmacy-benefit managers demand from manufacturers, who are increasingly being forced to compete with other drug makers and to offer better deals, which lowers drugs' effective cost.

In fact, the same report by IMS Health that found that list prices rose 12 percent last year also found that the net price growth — what insurers and employers actually pay for drugs — went up a far more modest 2.8 percent, one of the lowest increases in years.

But one of the cruelties of drug pricing is that the burden falls most heavily on those least able to pay it. Uninsured patients often must pay the list price of a drug, and an increasingly large share of insured customers are being asked to pay a percentage of the list price.

"It's sort of embedded in the health care system that the price is never the price, unless you're a cash-paying customer," said Adam J. Fein, president of Pembroke Consulting, a management advisory and business research company. "And in that case, we soak the poor."



J. Michael Pearson will be stepping down as chief executive officer of Valeant Pharmaceuticals next month. Hiroko Masuike/The New York Times

Some of the difference in prices is the result of actions taken by pharmacy-benefit managers like CVS Health, which manage drug plans for insurers. They have become more sophisticated in recent years, leading to better discounts from drug companies. They cite successes like the major discount that Gilead, the maker of an expensive new hepatitis C drug, conceded after AbbVie released a competing product.

And sales of expensive new cholesterol-lowering drugs, called PCSK9 inhibitors, have been sluggish, in part because insurers have placed numerous restrictions on their use.

“I think we’ve upped our game,” said Dr. Troyen Brennan, chief medical officer of CVS Health. “It’s much more dynamic and much more fast-paced, and I think that like us, the other P.B.M.s are responding much more rapidly.”

So if drug makers’ list prices aren’t representative of the true cost of a drug, why risk negative publicity by raising them? Many rebates and other discounts are tied to a percentage of the list price, which means a higher list price still yields more profit. And not every insurer and pharmacy-benefit manager is as sophisticated as the top players, so manufacturers can profit on the margins.

“The structure of the system is such that the only way they can get any increase in prices is to raise the list price by a very high percent,” said Mr. Fein. “It’s kind of baked into the system, and it’s so complicated, you can’t really unwind it without blowing up the entire health care system.”

Some of the most recent price increases may also be happening because drug makers are hoping to profit while they can, before congressional or other actions prevent them from doing so, said Geoffrey Porges, the author of the Leerink analysis.

“When you see this type of very aggressive pricing action across many products, then you start to scratch your head and say, is this the industry preparing for a more challenging price environment?” he said. “There’s just a general fear of the unknown.”

Drug makers say that, despite the intense focus on their industry, drug costs account for only around 10 percent of health care spending, an amount that has remained relatively steady over time.

“Obviously there’s a lot of variables that are used in determining what the appropriate prices are in any product,” said Dominic Caruso, the chief financial officer of Johnson & Johnson. “We price our products very responsibly, and in fact the list price increases that we’ve taken have been consistently below our competitive set over the last five years.”

Even though insurers and pharmacy-benefit managers are keeping drug prices in check in some areas, they are losing the battle in others, especially in areas like multiple sclerosis or cancer treatment, where a host of new drugs have recently entered the market with little competition.

“That’s where the real angst in the marketplace is,” said Dr. Miller. Specialty drugs, which are complex products that typically treat serious, chronic illnesses, now account for 33 percent of all drug spending even though they treat about 1 to 2 percent of all patients, Dr. Miller said.

“Pharma is looking at these lower numbers and saying, ‘We’re not as bad as you’re hearing in the marketplace,’” Dr. Miller said. But he said actual drug costs were still rising. “The main point is this is still faster than your income is growing. You’re falling further and further behind, and it’s not sustainable.”

Exhibit C

The New York Times | https://www.nytimes.com/2014/06/21/business/health-plans-bring-pressure-to-bear-on-drug-prices.html

Health Insurers Pressing Down on Drug Prices

By Andrew Pollack

June 20, 2014

6 MIN READ

In dealing with health plans, drug companies are facing a new imperative — bargain or be banned.

Determined to slow the rapid rise in drug prices, more health plans are refusing to cover certain drugs unless the companies charge less for them.

The strategy appears to be getting pharmaceutical makers to compete on price. Some big-selling products, like the respiratory medicine Advair and the diabetes drug Victoza, have suffered precipitous declines in market share because Express Scripts, the biggest pharmacy benefits manager, recently stopped paying for them for many patients.

“There’s clearly more price competition in the marketplace,” Andrew Witty, chief executive of GlaxoSmithKline, said, talking about Advair in a recent company earnings call.

Executives of pharmacy benefit management firms say they must do something to cope with rising prices, particularly for so-called specialty pharmaceuticals, which are used to treat complex diseases like cancer and multiple sclerosis.

Spending on specialty drugs rose 14.1 percent last year and by even greater amounts in previous recent years, according to Express Scripts. Most of that increased spending comes not from new drugs or new patients, but from price increases on older drugs that can often exceed 10 percent year after year.

Many other countries control drug prices in some manner, so drug companies have become dependent on increasing prices in the United States to grow.

Pharmaceutical companies rarely talk in detail about how they set prices or decide on price increases. They generally say that the price reflects the value of the medicine, which in some sense is a measure of what the market will bear.

They also say that insurers and government programs like Medicaid typically pay less than list price, though how much is usually kept confidential. If health plans are now winning bigger discounts or rebates, it will not show up in list prices but will help relieve pressure on insurance premiums.

That appears to be happening to some extent. Analysts at Credit Suisse estimate that the collective discounts and rebates for 15 large drug companies amounted to 31.9 percent of gross United States sales in 2013, up from 30.2 percent in 2012 and 19.7 percent in 2007.

How much bigger and broader discounting will become remains to be seen. Tim Anderson, pharmaceutical analyst at Sanford C. Bernstein & Company, said he had always been skeptical that pharmacy benefit managers could rein in prices.

“Express Scripts and other payers can talk tough whenever they want, but it only turns into reality when they have a drug company that is willing to break rank and play the price card,” he said. He said that drug companies, while not colluding, “have all looked at each other and said, ‘None of us needs to compete on price if we just hold the line.’ ”

But Mr. Anderson said that the recent developments with respiratory and diabetes drugs does suggest formularies are being tightened.

Formularies are lists of drugs that a health plan will cover. Typically they try to wring discounts from drug companies by offering better placement in the formulary. A less expensive drug will have a lower co-payment to encourage patients to use it.

But drug companies now help patients with their co-payments through coupons. That removes the incentive for patients to use the lower-priced drugs and lessens the incentive for drug companies to bargain.

In response, some pharmacy benefit managers are dropping some drugs from the formulary, rendering the co-payment cards ineffective. If patients want that drug, they have to pay full price by themselves.

CVS Caremark, the second-largest pharmacy benefit manager, started excluding about 30 drugs in 2012 and this year is excluding about 70 from the formulary used by many of its employer clients. Express Scripts this year began excluding 48 drugs or medical products, including Advair and Victoza.

Catamaran began offering an optional formulary this month that excludes 54 drugs.

With exclusions, bidding to get on the formulary becomes more of a winner-take-all contest. The winning companies gain more market share because rivals are excluded, so “they are willing to give us greater discounts,” said Dr. Steven Miller, chief medical officer of Express Scripts.

He said the new formulary, which covers more than 25 million people, would save about $700 million this year for clients who adopt it, or about 2 to 3 percent of their spending on drugs.

Jonathan C. Roberts, president of the pharmacy benefit management business at CVS Caremark, said there was an average combined savings for health plans and patients of $67 for each prescription switched from an excluded drug to a covered drug.

The new Express Scripts formulary went into effect for most patients in January, and the effect on prescriptions was swift.

Advair sales in the United States plummeted 30 percent in the first quarter, while sales of AstraZeneca’s Symbicort, a rival that remained on the formulary, grew 20 percent.

Novo Nordisk executives said that overall sales growth for this year would be about 2 percentage points lower than they would have been because Express Scripts had excluded both Victoza and Novo’s mealtime insulin products.

Other pharmacy benefit managers say they use exclusions more sparingly.

“We are seeing an increased request for these narrower formularies and excluded drugs,” said David Lassen, chief clinical officer at Prime Therapeutics, a pharmacy benefit manager owned by various Blue Cross and Blue Shield plans.

But he and some other executives said exclusions could cause disruptions for patients who must switch drugs. They can be used only when there are several equivalent drugs available, lest doctors and patients complain.

“You can’t just go for the least expensive,” said Dr. Brian K. Solow, chief medical officer of OptumRx, which is owned by the UnitedHealth Group. “You have to think about what is best for patients.”

In March, Medicare, under heavy pressure from drug companies, patient groups and Congress, abandoned a proposal to allow Medicare Part D plans to exclude some drugs for depression and schizophrenia.

Patients with Gaucher disease protested when UnitedHealthcare recently required virtually all patients to use just one of the three similar and very expensive therapies available for that disease. Patient groups have also expressed concern that health plans offered through the new insurance exchanges tend to have more exclusions and other restrictions on drugs than employer-funded plans.

Dr. Miller said the excluded drugs represented only a carefully selected 1 percent of drugs covered by Express Scripts and that the company had little problem switching patients.

The battle could escalate. Mr. Roberts said CVS next year would offer an optional formulary with 200 exclusions. Glaxo is now essentially offering to provide drugs affected by formulary restrictions free of charge to keep patients using its products.

Novo Nordisk executives said on the company’s first-quarter earnings call that the competitors who outbid them for the Express Scripts contract had not really gained much because they were paying higher rebates in exchange for a slightly higher market share. That might discourage companies from competing on price in the future.

“I would tend to believe the players will act to expand the segment if they have long-term interest in being in this field,” Novo’s chief executive, Lars Rebien Sorensen, said.

A big test of the strategy could come next year with drugs for hepatitis C. Health plans are worried about their ability to afford Sovaldi, a new drug from Gilead Sciences that costs $84,000 for a typical course of treatment. But AbbVie and Merck are expected to introduce competitive drugs, and the payers hope to pit one manufacturer against another to drive down prices.

The AbbVie chief executive, Richard Gonzalez, in response to a question in the company’s first-quarter call, suggested his company would compete on the merits of its product, not price.

“We have a product profile that stands up quite nicely in the marketplace, so that’s not our strategy going forward,” he said.

A top Pfizer executive made a similar comment when asked if the company should offer bigger discounts on Xeljanz, a new pill for rheumatoid arthritis that was excluded by Express Scripts.

But some executives say they sometimes have no choice but to deal.

“We are fighting to make sure that patients continue to have choice,” Enrique Conterno, who runs the diabetes business at Eli Lilly, said in his company’s call. Nonetheless, he added, “We need to be competitive whenever a payer basically makes the decision that they are going to narrow the formulary.”

Exhibit D

Inside The Secret World Of Drug Company Rebates

Matthew Herper Former Staff
I cover science and medicine, and believe this is biology's century.

May 10, 2012, 09:54am EDT

The free market is alive and well when it comes to drug prices – if you're an insurance company or a government program. But not if you're a consumer.

Top-selling pharmaceuticals, protected by patents, often seem priced in a manner that has little to do with the laws of supply and demand. Want that new cholesterol medicine ($2,000 per year), that cancer treatment ($60,000 per year) , or the medicine for your child's rare disease ($300,000 per year)? No negotiation. It's your money or your life.

But in fact drug companies are constantly negotiating, not with individuals but with payers – Medicare, Medicaid, insurers such as United Health Care and Aetna and pharmacy benefit plans such as Express Scripts . They don't reduce the price of their medicines. Instead, the drug firms pay rebates after the fact. For Medicaid, the price decreases are mandated by law, but everywhere else, free market forces are very much in effect. Me too drugs and those facing patent expiration have to deal with bigger rebates. Drug

firms annual price increases are partly a way to deal with all this rebating. Of course, if you're a person without health insurance buying medicines at the counter of Walgreen 's, you're stuck with the list price.

BETA

Rebates cut about $40 billion out of the drug industry's sales every year, says Pratap Khedkar, a principal at pharma marketing consultancy ZS Associates. We know that because the drug industry reports both its gross sales (before the rebates) and net sales (after the rebates are taken out). The size of the rebate average about 30% of a medicines sales, Khedkar says, and can be as low as single digits or as higher than 50% of gross sales.

"These may not be visible to the consumer," says Khedkar. "But between the insurance company and the pharma company, it is a very efficient free market."

What Drug Companies Give Back

Drug	IMS estimated U.S. sales ($Bil)	Company reported U.S. Sales ($Bil)	Estimated rebates (%)
Lipitor	$7.7	$5.0	35%
Plavix	$6.8	$6.6	3%
Nexium	$6.2	$2.4	61%
Abilify	$5.2	$4.0	24%
Advair	$4.6	$4.0	13%
Seroquel	$4.6	$3.3	27%
Singulair	$4.6	$3.5	23%
Crestor	$4.4	$3.1	30%
Cymbalta	$3.7	$3.2	14%

Humira	$3.5	$3.4	2%

Sources: IMS Health, company statements, analyst reports

No company reports how much of the gross sales of an individual drug are being given back to the payers. But there is a way to peer into the hidden world of pharma rebates. Every year, IMS Health, the prescription data tracking service, publishes its own lists of the most prescribed and the top-selling medicines in the country. But IMS' data capture gross sales at pharmacies, before the rebates happen. By comparing the gross sales reported by IMS to the sales the companies report to the Securities and Exchange Commission, it's possible to get an idea of how much of a medicine's gross sales are being given back in the form of rebates.

Caveats: there are other factors that could be affecting the difference, including if drug wholesalers are buying up extra inventory of a medicine, temporarily boosting sales. But generally speaking, I think we can assume that the bulk of these differences are from the rebates.

In the table in this story, I've calculated the difference between the IMS numbers and the numbers reported to the S.E.C. If U.S. sales were not immediately available, I took them from reports from sell-side analysts. The resulting figures show how greatly the numbers vary and give some hints as to why.

In the face of sudden generic discounts, Pfizer seems to have given a lot of rebates to keep Lipitor on insurance company formularies, giving up 35% of gross sales, up from 26% last year. (This matches up with reporting I did here; promotion of Lipitor is finally grinding to a halt.) By contrast, Bristol-Myers Squibb and Sanofi-Aventis, the makers of Plavix, only gave 2.6% of sales in rebates;

Plavix was until now the only medicine of its kind, and competitors from Eli Lilly and AstraZeneca have been unable to unseat it.

The most stunning discount is for Nexium, the purple pill for heartburn sold by AstraZeneca and derided by many as the perfect example of a me-too drug. Astra is giving back 60% of gross sales, most likely in the form of rebates. IMS lists Nexium as the third-best-selling drug in the country based on gross sales of $6.2 billion. But AstraZeneca reports U.S. Nexium sales of just $2.4 billion, putting it more on a par with Eli Lilly's cancer drug Alimta than behemoths like Lipitor and Plavix.

Why? As much as people rail against me-too drugs, being a me-too med is actually bad for the company, too. Insurers may be using the fact that they could direct consumers to generic Protonix or over-the-counter Prilosec or Prevacid as a bargaining stick, forcing Astra to cede ground.

Medicines in the same category seem to have the same level of discount. Astra's Crestor, a cholesterol drug that competes with Lipitor, seems to be giving 30% in rebates. The antipsychotics Seroquel (sold by AstraZeneca) and Abilify (from Otsuka & Bristol) give rebates of 27% and 24%, respectively.

AstraZeneca spokeswoman Stephanie Andrzejewski wrote via email that the company would not "discuss or disclose specifics around rebates" for Nexium. She added: "What I can tell you is that AstraZeneca is committed to helping people get the medicines they need and we understand our medicines won’t do patients any good if they can’t access them." She said it would be "inaccurate" to say AstraZeneca gave a 60% discount "across the board" – which is true. That appears to be the average discount.

The good news here is that, in the world of health insurers and drug giants, the free market is having an effect on drug prices. The bad news is that you have to be participating in this market by being insured in order to get those reduced rates. People who walk in off the street pay full price.